

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA; and	)	
the States of CALIFORNIA, DELAWARE,	)	
FLORIDA, GEORGIA, HAWAII,	)	Civil Action No. 09-CV-4264 (CDJ)
ILLINOIS, INDIANA, LOUISIANA,	)	
MASSACHUSETTS, MICHIGAN,	)	
MONTANA, NEVADA,	)	
NEW HAMPSHIRE, NEW JERSEY,	)	
NEW MEXICO, NEW YORK,	)	
OKLAHOMA, RHODE ISLAND,	)	
TENNESSEE, TEXAS, VIRGINIA,	)	
and WISCONSIN and the	)	
DISTRICT OF COLUMBIA, <i>ex rel.</i>	)	
AMY BERGMAN and	)	
AMY BERGMAN, individually,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
ABBOTT LABORATORIES,	)	
	)	
Defendants.	)	

**STATE OF TEXAS' STATEMENT OF INTEREST**

The State of Texas (Texas) files this Statement of Interest to correct statements made by Abbott Laboratories (Abbott) in its Defendant's Motion to Dismiss in the above-captioned case and its accompanying Memorandum of Law in Support of Defendant's Motion to Dismiss (Memorandum of Law) regarding the proper legal interpretation of the Texas Medicaid Fraud Prevention Act, chapter 36 of the Texas Human Resources Code (TMFPA). Texas retains an interest in this matter, even though it has declined to intervene, because Texas is entitled to a portion of any proceeds of the litigation diverted from the Texas Medicaid Program and because

Texas has an ongoing interest in ensuring consistent and correct interpretation of the TMFPA.

Texas respectfully submits the following positions:

**1. The elements of the unlawful acts under the Texas Medicaid Fraud Prevention Act (TMFPA) and the elements of common-law fraud under Texas law are not the same.**

Defendant asserts, “Each of the state-law claims includes fraud as an element of the action.” Memorandum of Law at 55. This assertion misrepresents the TMFPA’s provisions. The TMFPA proscribes conduct in terms of “unlawful acts.” *See* Tex. Hum. Res. Code § 36.002.

In contrast to the TMFPA’s unlawful acts, the elements of actionable common-law fraud in Texas are:

(1) that a material misrepresentation was made; (2) that it was false; (3) that, when the speaker made it, he knew it was false or made it recklessly without any knowledge of its truth and as a positive assertion; (4) that he made it with the intention that it should be acted upon by the party; (5) that the party acted in reliance upon it; and (6) that he thereby suffered injury.

*Trenholm v. Ratcliff*, 646 S.W.2d 927, 930 (Tex. 1983) (internal cites omitted). The TMFPA does not include elements 4-6 in the above quotation. There is no requirement to prove (1) that there must be an intention that the misrepresentation be acted upon, (2) that the Medicaid program relied upon the misrepresentation, or (3) that there be monetary injury. Therefore, the assertion that the TMFPA “includes fraud as an element” is incorrect.

**2. The TMFPA only partially “mirrors” the federal False Claims Act (FCA).**

Defendant also incorrectly characterizes the TMFPA as “mirroring” the FCA. *See* Memorandum of Law at 55 and 55 n.25. The TMFPA mirrors the FCA in certain respects, but it differs substantially from the FCA in others. For example, the TMFPA does not include or require the presentation of a “false claim.” Instead, the TMFPA sets out unlawful acts, such as knowingly making or causing to be made “a misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that

is greater than the benefit or payment that is authorized.” Tex. Hum. Res. Code § 36.002(1). *See, generally*, 31 U.S.C. §§ 3729(1)(A)-(G) and Tex. Hum. Res. Code §§ 36.002(1)-(13). The TMFPA also differs from the FCA in describing the liability incurred by the unlawful conduct. Where the FCA provides that a person who violates 31 U.S.C. § 3729(1)(A)-(G) is “liable to the United States Government for . . . 3 times the amount of damages which the Government sustains because of the act,” the TMFPA permits Texas to recover “the amount of any payment or the value of any monetary or in-kind benefit provided under the Medicaid program, directly or indirectly, as a result of the unlawful act, including any payment made to a third party.” 31 U.S.C. § 3729(1) and Tex. Hum. Res. Code §§ 36.052(a)(1).

The differences, where they exist, between the FCA and the TMFPA are material and must be carefully considered in applying Texas law to the specific facts of every case, both in determining liability and in assessing appropriate civil remedies. As the Texas Supreme Court has held, “[W]hen the Legislature looks to another jurisdiction’s statute, but modifies rather than adopts some of its provisions, it does so purposefully.” *Helena Chemical Co. v. Wilkins*, 47 S.W.3d 486, 497 (Tex. 2001). A blanket assertion that the TMFPA “mirrors” the FCA is incorrect, and applying FCA case law to the TMFPA must be undertaken with great caution.

**3. The Relator is allowed to pursue claims on behalf of the State of Texas pursuant to the TMFPA for the time period January 1, 1995 to the present.**

Abbott asserts that the Relator “is barred” from pursuing “false claims” on or before May 4, 2007. Memorandum of Law at 55 n. 29. The TMFPA permits the Relator to pursue claims for the same time period that the State could pursue unlawful acts — from the effective date of the statute, which is September 1, 1995.

When “*qui tam*” provisions were added to the TMFPA in 1997, the provisions precluded Relators from pursuing an action if the State did not intervene. The TMFPA provided that,

should the state decline to take over the action, the court “shall dismiss” the action. Tex. Hum. Res. Code § 36.104(b) (eff. Sept. 1, 1997). This section was amended in 2007 to permit a Relator to proceed without the state’s participation. Tex. Hum. Res. Code § 36.104(b) (eff. May 4, 2007).

Abbott argues that the 2007 amendments, which included changes to more than this one section, limit the Relator’s ability to recover for unlawful acts committed before May 4, 2007, the date on which all the amendments became effective. The relevant 2007 language reads,

“This Act applies only to conduct that occurs on or after the effective date [May 4, 2007] of this Act. Conduct that occurs before the effective date of this Act is governed by the law in effect at the time the conduct occurred, and that law is continued in effect for that purpose.” Texas Acts 2007, 80<sup>th</sup> Legis., ch. 29, § 6, eff. May 4, 2007.

Texas disagrees with Abbott’s interpretation of this language. The application of this provision to the changes made in §36.104 refers to the State’s decision to intervene. The decision to intervene is the “conduct” at issue—not the unlawful acts delineated in section 36.002. In other words, for lawsuits in which the State elected not to intervene prior to May 4, 2007, the Relator may not go forward alone. Beginning May 4, 2007, the State’s election not to intervene, the conduct addressed by the 2007, amendment to §36.104, does not foreclose the Relator’s ability to proceed.

The State’s interpretation of section 36.104 is consistent with amendments to other sections of the Act. For instance, section 36.103 was amended in 2005 and the same provisions regarding application of that amendment were included to that amendment.<sup>1</sup> See Tex. Hum. Res.

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<sup>1</sup>“(a) This Act applies only to conduct that occurs on or after the effective date of this Act. Conduct that occurs before the effective date of the Act is governed by the law in effect at the time the conduct occurred, and that law is continued in effect for that purpose. (b) For purposes of this section, conduct constituting an offense under the penal law of this state occurred before the effective date of this Act in any element of the offense occurred before that date.” Texas Acts, 79<sup>th</sup> Legis., ch. 806, § 20 eff. Sept. 1, 2005.

Code § 36.103; Texas Acts 2005, 79<sup>th</sup> Legis., ch 806, § 20. Section 36.103 addresses the timing of a defendant's answer to a TMFPA petition. Clearly, the "conduct" referred to is the answer of the defendant. The word "conduct" must be construed in context to give effect to Legislative intent. It must apply to conduct with is the subject of the amendment, not to unlawful acts from other sections of the TMFPA.

Standard rules of statutory construction under Texas law lead to no other interpretation of the word "conduct" in this context. It is presumed that, in enacting a statute, the public interest is favored over any private interest. Tex. Gov't Code § 311.021(5). The public interest served in enacting the 2007 amendment to §36.104 is to expand the ability of the State to recover funds unlawfully diverted from the Texas Medicaid Program. That public interest is subverted by Defendant's interpretation. In construing a statute, the court's "primary goal is to ascertain and give effect to the Legislature's intent in enacting it." *In re Canales*, 52 S.W.3d 698, 702 (Tex. 2001). Whether or not statutory language is ambiguous, a court "may consider, among other things, the statute's objectives, its legislative history, and the consequences of a particular construction." *Id.*

The word "conduct," used in this context, has been construed differently by federal district courts in Texas. Compare *United States ex rel. King v. Solvay S.A.*, 823 F.Supp.2d 472, 521-522 (S.D.Tex. 2011), with *United States ex rel. Wall*, 778 F.Supp.2d 709, 724 (N.D.Tex. 2011). Texas agrees with the Court's conclusion in *King*, holding the " 'conduct' discussed in section 36.104 is the State of Texas's election not to intervene." *Id.* at 522. This is the only reasonable interpretation. The State's ability to sue for unlawful acts dating back to the effective date of the statute, September 1, 1995, is unquestioned. Allowing Relators to pursue TMFPA suits without the participation of the State — allowed for the first time by the 2007 amendment

to § 36.104 — is clearly intended to enhance the State’s potential for recoveries without incurring additional costs. Restricting the Relator to unlawful acts committed after May 4, 2007, defeats that intent. The Texas Supreme Court instructs, “To determine legislative intent, we examine the old law, the evil to be corrected, and object to be obtained.” *Barshop v. Medina County Underground Water Conservation District*, 925 S.W.2d 618, 629 (Tex. 1996). The old law only permitted suits to be pursued if the State intervened. The evil to be corrected was the burden placed on the State to either intervene or forego recovery. This burden effectively limited the State’s ability to recover. The object to be obtained was the enhanced ability to recover Medicaid dollars wrongfully diverted from the program by empowering Relators to pursue claims on behalf of the State alone. Therefore, Abbott’s assertion that the Relator should be barred from claims before May 4, 2007 finds no support in the properly-interpreted language of the statute and should be rejected.

**4. The Relator is not subject to a statute of limitations.**

Abbott wrongly asserts a statute of limitations applies to claims pursued here by the Relator on behalf of the State of Texas.<sup>2</sup> See Memorandum of Law at 58 n. 29, 62 n. 47, 63, 63 n. 50. Texas disagrees. The TMFPA is not subject to a statute of limitations, whether the State or the Relator or both pursue the suit.

First, Texas, again, turns to standard rules of statutory construction followed by Texas courts. The primary rule of statutory construction in Texas is to give effect to the intent of the Legislature. *Cash America Int’l Inc. v. Bennett*, 35 S.W.3d 12, 16 (Tex. 2000); *Fitzgerald v. Advanced Spine Fixation Systems, Inc.*, 996 S.W.2d 864, 865 (Tex. 1998). It is “cardinal law in Texas” that a court accomplishes this purpose, “first, by looking to the plain and common

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<sup>2</sup> In support of this contention, Defendants cite *United States ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F.supp.2d 805, 817-18 (E.D. Tex. 2008). For the reasons argued here, Texas strongly disagrees with this holding.

meaning of the statute's words." *Fitzgerald*, 996 S.W.2d at 865 (quoting *Liberty Mut. Ins. Co. v. Garrison Contractors*, 966 S.W.2d 482, 484 (Tex. 1998)); accord *Albertson's, Inc. v. Sinclair*, 984 S.W.2d 958 (Tex. 1999). The general rule is that "all statutes are presumed to be enacted by the legislature with full knowledge of the existing conditions of the law." *Driscoll v. Harris County Comm'rs Court*, 688 S.W.2d 569, 574 (Tex. App.—Houston [14th Dist.] 1984, writ ref'd n.r.e.) (citing *McBride v. Clayton*, 166 S.W.2d 125, 128 (Tex. Comm'n App. 1942)). In construing a statute, a court may insert additional words into a statutory provision only when it is necessary to give effect to clear legislative intent. *Fitzgerald*, 996 S.W.2d at 867.

Second, it is long-standing Texas law that the State is not subject to a statute of limitations unless a statute so expressly provides. *Brown v. Sneed*, 14 S.W. 248, 251 (Tex. 1890). This holding rests on doctrine of sovereign immunity. *Id.* In permitting actions by private persons in the TMFPA, the Legislature expressly provided that sovereign immunity is not waived. Tex. Hum. Res. Code § 36.116. Nor does the TMFPA impose a statute of limitations on the State *or* the Relator. Supplying one violates a fundamental rule of statutory construction that a court "should read every word, phrase, and expression in a statute as if were deliberately chosen, and presume the words excluded from the statute are done so purposefully." *Gables Realty Ltd. Partnership v. Travis Central Appraisal Dist.*, 81 S.W.3d 869, 873 (Tex. App.—Austin 2002, pet. denied) (internal cites omitted) (emphasis added). In adopting this amendment to § 36.104, the Legislature did look to the FCA, which always permitted Relators to proceed without the Government, but, significantly, the Legislature of Texas chose not to adopt the FCA's statute of limitations. Again, this omission of a statute of limitations should be recognized by this Court, under the holding of the Texas Supreme Court cited *supra*: "[W]hen the

Legislature looks to another jurisdiction's statute, but modifies rather than adopts some of its provisions, it does so purposefully." *Helena Chemical Co.*, 47 S.W.3d at 497 (Tex. 2001).

Simply stated, the Texas Legislature did not adopt a statute of limitations applicable to the TMFPA; therefore, one should not be imputed by this Court.

**5. A defendant that engages in off-label marketing in violation of the federal Food, Drug and Cosmetics Act (FDCA) may be liable under the TMFPA.**

Abbott argues that allegations of violations of the FDCA cannot support a False Claims Act claim because they are not sufficient allegations of "false claims for payment made to the government." Without commenting on the validity of Abbott's argument with regard to the False Claims Act, it is important to note, once again, that the language of the TMFPA is not identical to the language of the federal False Claims Act. Due to the differences in the language of the two statutes, Abbott's argument does not apply to the TMFPA. The majority of the unlawful acts enumerated in the Texas statute do not depend upon the making or submission of a false claim. Texas has successfully recovered hundreds of millions of dollars for the Texas Medicaid program in off-label marketing cases pursuing liability under the following provisions of the TMFPA:

Sec. 36.002. UNLAWFUL ACTS. A person commits an unlawful act if the person:

(1) knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;

(2) knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;

(4) knowingly makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:

(B) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;



Each of these unlawful acts describes liability under the TMFPA without including the making or submission of a false claim as an element. Several factual scenarios demonstrate there is no need to prove the making or submission of a false claim for payment to establish TMFPA liability in an off-label case. For instance, the TMFPA is violated if a manufacturer, in the process of obtaining the benefit of its product's inclusion on the Texas Medicaid formulary, makes a misrepresentation to the Texas Medicaid program that the drug is not in violation of state or federal law, when in fact the drug is misbranded due to off-label promotion in violation of the FDCA. Additionally, failing to disclose to the Texas Medicaid program that a drug is being promoted off-label to Texas Medicaid providers gives rise to TMFPA liability. TMFPA liability can also occur when a manufacturer misrepresents the appropriate use of its drug to the Texas Medicaid program, such as in instances when the drug is marketed for use in an off-label patient population for which neither safety nor efficacy has been established.<sup>3</sup>

**6. Texas Medicaid is not authorized to reimburse a pharmacy for filing prescriptions for a drug that does not meet the definition of a covered outpatient drug.**

As a general rule, a drug prescribed for a use for which there is no FDA approval or support in one of several designated compendia does not meet the definition of a covered outpatient drug. *See* 42 U.S.C. §1396r-8(k)(3),(6); 42 U.S.C. §1396r-8(g)(1)(B)(i). As noted in the affidavits of two former Texas Medicaid officials (Martha McNeill's affidavit attached as

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<sup>3</sup>In January, 2012, after seven days of the presentation of the State's case, Johnson & Johnson settled a TMFPA suit brought by Texas alleging off-label marketing of the atypical antipsychotic drug, Risperdal, for \$158 million. Prior to trial, Defendants argued that allegations of misrepresenting the safety, efficacy, and appropriate use of Risperdal to the Medicaid program, thus promotion its use off-label to vulnerable patient populations such as children and adolescents, did not constitute allegations of unlawful acts under the TMFPA. The trial judge, the Honorable John K. Dietz, rejected Defendants' arguments and found the off-label allegations did fall constitute unlawful acts under the TMFPA. *See* Order on Defendants' Special Exceptions to Plaintiffs' Fourth Amended Petition, *The State of Texas ex rel. Allen Jones v. Ortho-McNeil Pharmaceutical, LLC, McNeil Consumer Healthcare Division of McNeil PPC, Inc., Janssen Ortho, LLC, Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Johnson*, Cause No. D-1-GV-04-001288, In the 250<sup>th</sup> District Court of Travis County, Texas, attached hereto as Exhibit C.

Exhibit A and Leslie K. Budnek Harper's affidavit attached as Exhibit B), Texas Medicaid would not reimburse a pharmacy for any prescription had it learned at any time before or after the claim was submitted that the prescription did not meet the definition of a covered outpatient drug. Abbott argues that if a state Medicaid program chooses to reimburse a claim for a drug prescribed for off-label use, liability cannot attach for reimbursement. That argument fails to recognize the reality that, in most instances, when a pharmacy claim is presented for payment, the state Medicaid program does not know whether or not the drug is being prescribed for an off-label use. To analyze each and every prescription claim to determine in real time whether it is being prescribed off-label would bring Medicaid claims processing to a virtual standstill. The reality is that prescriptions are unknowingly reimbursed by state Medicaid programs every day that do not meet the definition of a covered outpatient drug. The fact that those reimbursements were made does not mean the payments were authorized under the Medicaid statute—clearly they are not. The TMFPA allows for recoupment of the unauthorized reimbursements. In supporting its argument, Abbott relies upon *United States of America ex rel. James Banignan* [sic] v. *Organon USA Inc.*, No. 07-12153-RWZ, 2012 WL 1997874 (D. Mass. June 1, 2012). Abbott represents to this Court that “In *Banignan* [sic], the district court dismissed the complaint based on the coverage discretion possessed by the states under the Medicaid statute because the relators failed to show that the states did not cover off-label, non-compendium prescriptions.” Abbott failed to advise the Court that off-label marketing claims against the Organon defendants under the TMFPA were not dismissed. See *Banignan* [sic] at \*17.

Respectfully submitted,

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ATTORNEYS FOR THE STATE OF TEXAS

**CERTIFICATE OF SERVICE**

I hereby certify that on this 20<sup>th</sup> day of November 2012, a true and correct copy of the foregoing *State of Texas' Statement of Interest* was filed and served via electronic case filing (ECF) upon all counsel of record who have consented to electronic service and that it is available for viewing and downloading from the ECF system. I further certify that if any party has not consented to electronic service, that a true and correct copy was served upon them by first class mail, postage prepaid as follows:

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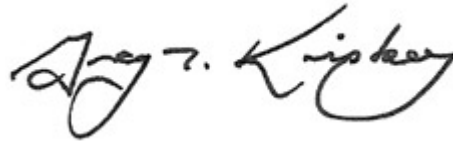
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A handwritten signature in black ink, reading "Greg T. Kinsky". The signature is fluid and cursive, with the first name "Greg" and last name "Kinsky" clearly distinguishable.

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GREG T. KINSKEY

# EXHIBIT A

**AFFIDAVIT OF MARTHA MCNEILL**

**STATE OF TEXAS**

§

**COUNTY OF TRAVIS**

§

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**BEFORE ME**, the undersigned notary public, on this day personally appeared Martha McNeill, who is personally known to me and who being by me duly sworn on her oath deposed and stated:

1. My name is Martha McNeill. I am over the age of eighteen, of sound mind, literate in the English language and otherwise fully competent to testify to the matters stated herein. I am employed by the State of Texas as the Director of Product & Prescriber Management for the Texas Health and Human Services Commission and the Texas Medicaid Program ("Texas Medicaid"). I have read the following affidavit and every fact and statement contained therein is true, correct, and within my personal knowledge.

2. I have held my present position for 10 years. In that time, my duties have included managing the Vendor Drug Program formulary and prescriber databases and administering the out-patient drug formulary for two Texas Health Department and two Health and Human Services Commission programs and the prescriber data base used for claims adjudication or other administrative functions within the Medicaid/CHIP Benefits program. In addition to my experience in the Texas Medicaid program, I have experience in the following subject areas relating to prescription drug reimbursement in Medicaid: work as both a staff pharmacist and relief pharmacist for independent pharmacies, work as a staff pharmacist as well as the manager of chain pharmacies.

3. I have reviewed and I am familiar with the various federal and state rules regarding the eligibility of prescription products for reimbursement within the Texas Medicaid Program.

4. In order for a particular claim to be eligible for reimbursement, there are several payment prerequisites that must be met. The following is a list of several requirements that must be satisfied:

- (a) The patient receiving the medication must be an eligible Medicaid recipient;
- (b) The physician who wrote the prescription must be a physician licensed to practice in the State of Texas;
- (c) The pharmacy seeking reimbursement must be a Medicaid provider and have a signed provider agreement, which includes various express certifications;
- (d) The pharmacy must have actually dispensed the medication, and cannot have received payment, whether in whole or in part, apart from appropriate co-pay payments, from any other source;
- (e) The claim must be submitted in conformity with the applicable claim submission procedures, including the making of various express certifications; and
- (f) The claim must be for a drug that is eligible for reimbursement and prescribed for a purpose that is covered by Medicaid.

5. Determining whether a drug is eligible for reimbursement and prescribed for a purpose that is covered by Medicaid is governed by 42 U.S.C. § 1396r-8; Texas Administrative Code, Title 1, Chapter 354, Subchapters F & W; and the Provider's Manual. See 1 T.A.C. § 354.1831.

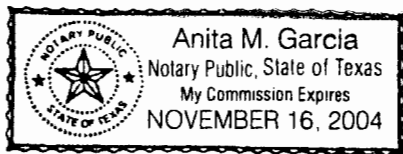
6. Under various NDC codes, the drug Neurontin has been on the Texas Medicaid formulary since 12/30/93. Since that date, Neurontin has remained on the formulary and has been eligible for reimbursement by Medicaid for dispensation to qualified Medicaid recipients.

7. Texas Medicaid would not have reimbursed a pharmacy for any Neurontin prescription claim had it learned, at any time before or after the claim was submitted, that the prescription did not meet the definition of a covered outpatient drug.

8. Further Affiant sayeth not.

Martha McNeill  
MARTHA MCNEILL

SWORN TO and SUBSCRIBED before me by Martha McNeill on this 15th day of May,  
2003, to certify which witness my hand and seal of office.



Anita M. Garcia  
NOTARY PUBLIC in and for the  
State of Texas

My Commission Expires: 11/16/04

# EXHIBIT B

CAUSE NO. D-1-GV-04-001288

STATE OF TEXAS	§	IN THE DISTRICT COURT
ex rel.	§	
ALLEN JONES,	§	
	§	
Plaintiffs,	§	
v.	§	250 <sup>TH</sup> JUDICIAL DISTRICT
	§	
JANSSEN, L.P., JANSSEN	§	
PHARMACEUTICA, INC.,	§	
ORTHO-McNEIL PHARMACEUTICAL,	§	
INC., McNEIL CONSUMER &	§	
SPECIALTY PHARMACEUTICALS,	§	
JANSSEN ORTHO, LLC, and	§	
JOHNSON & JOHNSON,	§	
	§	
Defendants.	§	TRAVIS COUNTY, TEXAS

**AFFIDAVIT**

THE STATE OF TEXAS   §  
                                  §  
COUNTY OF TRAVIS   §

BEFORE ME, the undersigned authority, personally appeared Leslie K. Budnek Harper, who, being by me duly sworn, made the following statements:

1. "My name is Leslie K. Budnek Harper. I am above the age of 18, of sound mind, and capable of making this affidavit. I have never been convicted of a felony and the facts stated herein are within my personal knowledge and are true and correct.
2. From October 1999 through May 2005, I was employed as the formulary analyst for the Vendor Drug Program (VDP) of Texas Medicaid. As the formulary analyst, my primary responsibility was to review VDP questionnaires submitted by drug companies to determine if the criteria were met for a drug to be reimbursed by Texas Medicaid.
3. From my experience as the formulary analyst at Texas Medicaid VDP, I know that state Medicaid law requires a drug company to complete the VDP questionnaire in order to apply to obtain the benefit of having its drug listed on the Texas Drug Code Index (TDCI), which is commonly referred to as the Texas Medicaid outpatient formulary. (I will refer to the TDCI as "the formulary" in this affidavit.) The state Medicaid law that contains this requirement is Texas Administrative Code § 354.1921. A pharmacist filling a prescription for a Texas Medicaid recipient can only be reimbursed for the drug if it is listed on the formulary.

4. I also know from my experience as the formulary analyst at Texas Medicaid VDP that in order to complete the VDP questionnaire, a drug company must provide VDP with product labeling information for the drug, such as the package insert or materials for physicians, as well as FDA letters documenting approval and approval for marketing. These documents are an essential part of the application process to have the drug listed on the formulary and reimbursed by Texas Medicaid.
5. As part of my job responsibilities as the formulary analyst for Texas Medicaid VDP, I relied upon information provided to VDP by drug companies in response to the VDP questionnaire in determining whether or not the criteria had been met to add the product to the formulary. Truthful and complete information was required. The drug companies were required to certify that the information they provided was correct and that the product was not in violation of state or federal law at the time the questionnaire was submitted. The VDP questionnaire also required drug companies to update VDP by notifying the program of any changes pertaining to any of the information requested on the questionnaire.
6. I did receive updated product information, such as materials for physicians, from certain drug companies during my tenure as the VDP formulary analyst.
7. As part of my job duties as the VDP formulary analyst, I reviewed each drug company request to add a drug to the formulary (or questionnaire) to determine the need to add the drug and to determine the need for reimbursement restrictions, as described in the state Medicaid law contained in Texas Administrative Code § 354.1923. The determination of the need for reimbursement restrictions is in line with Texas Medicaid's drug use review (DUR) responsibilities mandated by the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) and enhances Texas Medicaid's ability to discharge its DUR obligations to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.
8. As the VDP formulary analyst, I received some applications that contained incomplete information and I directed VDP staff to return the questionnaires as described in Texas Administrative Code § 354.1923, which calls for VDP to return questionnaires upon the discovery of false, misleading or incomplete information or documentation.
9. Risperdal had already been added to the formulary when I became the VDP formulary analyst in 1999.
10. Additional VDP questionnaires were required to be submitted to Texas Medicaid each time a request was made to add a new formulation of Risperdal to the formulary. Two questionnaires for new formulations of Risperdal were submitted while I was the VDP formulary analyst. One was submitted by Johnson & Johnson in May of 2003 for Risperdal M-Tabs. The other was submitted by Johnson & Johnson in November of 2003 for Risperdal Consta.



11. Had I discovered that either of those Risperdal formulations was misbranded in violation of both the Texas and United States Food Drug and Cosmetics Acts and thus in violation of both state and federal law, I would have directed VDP staff to return the questionnaires to Johnson & Johnson as described in Texas Administrative Code § 354.1923. The reason is because the questionnaires would have contained false information in the certification, which stated that the product was not in violation of state or federal law. Just as I directed VDP staff to return incomplete questionnaires, I would have done the same with questionnaires I knew to contain false information.
12. Additionally, had I discovered that either of those new Risperdal formulations was misbranded and thus in violation of state and federal law, I would have immediately notified my colleagues at Texas Medicaid. Based upon my experience working at Texas Medicaid VDP, I believe it is highly probable that Texas Medicaid coverage of Risperdal would have been terminated in the most expeditious manner, to avoid Texas Medicaid reimbursement for a drug that was in violation of state and federal law.
13. As the Texas Medicaid VDP formulary analyst, I was aware that federal Medicaid law required that, in order for a pharmacy claim for reimbursement to be eligible for payment, the claim must be for a drug that meets the definition of a covered outpatient drug. My understanding was that, as a general rule, a drug prescribed for a use for which there is no FDA approval or support in one of several designated compendia, does not meet the definition of a covered outpatient drug. My understanding was that Medicaid reimbursement for drugs prescribed for a use for which there was no FDA approval or designated compendia support was not authorized. It was my understanding that Texas Medicaid would not have reimbursed a pharmacy for any prescription, including any Risperdal prescription, had it learned at any time before or after the claim was submitted that the prescription did not meet the definition of a covered outpatient drug. The state and federal Medicaid laws that relate to whether a drug is eligible for Medicaid reimbursement are 42 U.S.C. § 1396r-8; Texas Administrative Code, Title 1, Chapter 354, subchapter F & W; and the Texas Medicaid Provider's Manual."

"Further Affiant Sayeth Not."

Leslie K. Budnek Harper  
AFFIANT

Before me, Mary Jo Toupin, a Notary Public in and for The State of Texas on this day personally appeared Leslie K. Budnek Harper, personally known to me and proved through submission of Texas Drivers License No. 03495542 to be the same person whose name is subscribed to the foregoing instrument and, being by me first duly sworn, declared that the statements therein contained are true and correct.

Given under my hand and seal of office this 7<sup>th</sup> day of January, 2011.

Mary Jo Toupin  
NOTARY PUBLIC IN AND FOR THE STATE OF TEXAS

